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NEW ALBERTSON'S, INC.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

RAYMOND W. LONDON, on behalf of Himself and All Others Similarly Situated, Plaintiff, vs. NEW ALBERTSON'S, INC.; CERBERUS CAPITAL MANAGEMENT (CALIFORNIA), LLC; and DOES 1 through 25, inclusive, Defendants.	CASE NO.: 08-1173 HC AB Assigned to: Hon. Marilyn Huff **DECLARATION IN SUPPORT OF MOTION TO DISMISS** **Hearing:** Date: August 11, 2008 Time: 10:30 a.m. Courtroom: 13, Fifth Floor Complaint filed: May 29, 2008

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I, KATHLENE W. LOWE, declare:

1. I am a Partner with the law firm of Dorsey & Whitney LLP, counsel of record for Defendant New Albertson's, Inc. ("Albertsons") in this action. I have personal knowledge of the following or knowledge based upon relevant business records and information and if called as a witness, could competently testify thereto.

2. Attached as **Exhibit A** is a true and correct copy of the legislative history of Assembly Bill 262 ("AB 262"), which I obtained from the Legislative Intent Service. Among other things, the Bill History states that the AB 262 "Died in Conference" on November 30, 2004.

3. Attached as **Exhibit B** is a true and correct copy of a report of the California Senate Committee on Business and Professions, showing a hearing date of August 19, 2003, regarding AB 262. At page 2 of the report, the authors note that this bill "[p]rohibits a person from transmitting, selling, or releasing to a third party, in exchange for remuneration, any prescribing data of a physician, if the physician has placed his or her name on a DO NOT USE list maintained by the Board on its Web-site . . . ."

4. At page 4 of Exhibit B, the authors comment (at Point 1) that AB 262 contained "two major parts, one sponsored by the Office of HIPAA Implementation . . . relating to CMIA and medical marketing, and the other sponsored by the California Medication Association (CMA) relating to the sale of physician prescribing data."

5. At page 9 of Exhibit B, the authors comment that "[i]t seems clear that the CMIA was intended to apply to patient medical information and not physician prescription information which may or may not be made available to other persons or entities depending on the specified restrictions with Section 56.268."

6. Attached as **Exhibit C** is a true and correct copy of a report by the California Senate Rules Committee on Assembly Bill 715 ("AB715"). It explains, at pages 1-2, that AB 715 contains the portion of AB 262 which related to the CMIA and medical marketing (i.e., one of the two portions of AB 262 discussed at Paragraph 4 above). On page 3, it notes that AB 262 contained provisions relating both to medical marketing and to physicians' proposed DO NOT USE list.

7. The legislative history comments following the text of Civil Code Section 56.10(d) in West's Annotated California Codes confirm that the amendment which added the "use for marketing" prohibition to the CMIA in 2004 was contained in AB 715. For the convenience of the Court and all counsel, a copy of that page is attached as **Exhibit D.**

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Signed on July 10, 2008, in Irvine, California.

/KATHLENE W. LOWE

EXHIBIT A

History of AB 262 (2003)

http://www.leginfo.ca.gov/pub/03-04/bill/asm/ab_0251-0300/ab_262_bill_20041130_history.html

COMPLETE BILL HISTORY

BILL NUMBER : A.B. No. 262
AUTHOR : Chan
TOPIC : Pharmacies: physician prescribing data.

TYPE OF BILL :
Inactive
Non-Urgency
Appropriations
Majority Vote Required
State-Mandated Local Program
Fiscal
Non-Tax Levy

BILL HISTORY
2004
Nov. 30 Died in Conference.
Aug. 28 Assembly refused to concur in Senate amendments. To Conference Committee. (Ayes 37. Noes 34. Page 8068.)
Aug. 27 Joint Rule 62(a), file notice suspended. (Page 7971.) From committee: With recommendation: That Senate amendments be concurred in. (Ayes 10. Noes 3.) (August 27).
Aug. 26 Assembly Rule 77 suspended. (Page 7802.) Re-referred to Com. on HEALTH. pursuant to Assembly Rule 77.2.
Aug. 25 In Assembly. Concurrence in Senate amendments pending. May be considered on or after August 27 pursuant to Assembly Rule 77.
Aug. 25 Read third time, passed, and to Assembly. (Ayes 22. Noes 15. Page 5330.)
Aug. 23 Read third time, amended, and returned to third reading.
Aug. 17 Read second time, amended, and to third reading.
Aug. 16 From committee: Amend, and do pass as amended. (Ayes 7. Noes 4.).
Aug. 4 In committee: Placed on Appropriations suspense file.
July 29 In committee: Hearing postponed by committee.
July 7 Read second time, amended, and re-referred to Com. on APPR.
July 6 From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 5. Noes 2.).
June 30 Joint Rule 62(a), file notice suspended. (Page 4494.)
June 29 In committee: Set first hearing. Failed passage. Reconsideration granted.
June 23 Re-referred to Com. on JUD.
June 22 From committee: Do pass, and re-refer to Com. on RLS. Re-referred. (Ayes 6. Noes 0.).
June 21 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B. & P.
June 9 Re-referred to Com. on B. & P.
June 7 Withdrawn from committee. Re-referred to Com. on RLS.
June 3 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on APPR.

Jan. 6 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on APPR.

2003

Aug. 28 In committee: Hearing postponed by committee.

Aug. 27 Joint Rule 62(a), file notice waived. (Page 2158.)

Aug. 26 Withdrawn from committee. Re-referred to Com. on RLS. Re-referred to Com. on APPR.

Aug. 25 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B. & P.

Aug. 18 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B. & P.

July 24 Re-referred to Com. on B. & P.

July 22 Read second time, amended, and re-referred to Com. on RLS.

July 21 From committee: Amend, do pass as amended, and re-refer to Com. on RLS. (Ayes 5. Noes 1.).

July 10 Joint Rule 61(a)(9) suspended. (Page 1731.)

July 8 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on JUD.

May 29 Referred to Com. on JUD.

May 20 In Senate. Read first time. To Com. on RLS. for assignment.

May 19 Read third time, passed, and to Senate. (Ayes 76. Noes 0. Page 1751.)

May 12 Read second time. To third reading.

May 8 From committee: Do pass. (Ayes 24. Noes 0.) (May 7).

Apr. 30 Re-referred to Com. on APPR.

Apr. 29 Read second time and amended.

Apr. 28 From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 22. Noes 1.) (April 22).

Mar. 27 Re-referred to Com. on HEALTH.

Mar. 26 Read second time and amended.

Mar. 25 From committee: Amend, do pass as amended, and re-refer to Com. on HEALTH. (Ayes 13. Noes 0.) (March 18).

Mar. 13 Re-referred to Com. on JUD.

Mar. 12 From committee chair, with author's amendments: Amend, and re-refer to Com. on JUD. Read second time and amended.

Feb. 24 Re-referred to Com. on JUD. by unanimous consent, and then be re-referred to Com. on HEALTH.

Feb. 11 Referred to Coms. on HEALTH and JUD.

Feb. 5 From printer. May be heard in committee March 7.

Feb. 4 Read first time. To print.

EXHIBIT B

Hearing Date: August 19, 2003 Bill No: AB 262

SENATE COMMITTEE ON BUSINESS AND PROFESSIONS

Senator Liz Figueroa, Chair

Bill No: AB 262 Author: Chan
As Amended: August 18, 2003 Fiscal: Yes

SUBJECT: Personal information.

SUMMARY: This bill prohibits health care providers and plans from receiving payment from third parties to send marketing materials to their patients, except in certain limited circumstances, and prevents any person from selling or releasing physician prescribing data to a third party if his or her name is on a "DO NOT USE" list maintained by the Medical Board, unless for specified purposes.

Existing federal law, the federal Health Insurance Portability and Accountability Act (HIPAA):

1) Provides that a health care provider or plan may not market to a patient without prior authorization.

2) Exempts the following practices from the definition of "marketing":

   a) communications made to describe a health-related product or service that is provided by, or included in a plan of benefits of the provider, or

   b) communications made for the treatment of the individual, or

   c) communications made for case management or care coordination, or the recommended alternative treatments to an individual.

Existing state law, the Confidentiality of Medical Information Act (CMIA):

1) Provides that no health care provider or plan shall intentionally share, sell, or otherwise use medical information for any purpose except as authorized in law or where the patient has consented.

2) Provides that medical information may be disclosed to a third party for purposes of "disease management programs," which are defined as services administered to patients in order to improve their overall health utilizing cost-effective, evidence-based, or consensus-based practice guidelines and patient self-management strategies.

3) Defines "prescription" as an oral, written, or electronic transmission order given individually for the person or persons for whom ordered that includes specified information including the name of the patient, the name and quantity

of the drug prescribed and directions for use, and the conditions for which the drug was prescribed if requested by the patient.

4) Allows the issuance of a prescription by a licensed physician, dentist, optometrist, podiatrist, certified nurse-midwife, nurse practitioner, or physician assistant if so authorized.

5) Requires all prescriptions filled by a pharmacy to be maintained on the premises and available for inspection by authorized officers of the law.

6) Provides that it shall be unprofessional conduct for a pharmacist to violate any provisions of law governing pharmacy.

7) Provides for the licensing and regulation of physicians and surgeons by the Medical Board (Board).

This bill:

1) Defines "marketing" as making a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

2) Excludes from the definition of "marketing" the following:

   a) communications for which the communicator does not receive direct or indirect remuneration;

   b) certain communications made to a current enrollee of a provider network or health plan regarding how the plan works and can be utilized;

   c) communications by a provider that are tailored to the circumstances of a particular individual for treatment purposes;

   d) communications by a provider or plan in the course of managing the treatment of the individual, or for the purpose of recommending alternative treatments to the individual, so long as the communicator is not receiving remuneration for the communication; and,

   e) communications for disease management programs for a seriously debilitating or life-threatening condition where the provider or plan receives remuneration, however, requires the communicator to inform the individual that the communication is paid for by a third party and to provide the individual with an "opt out" for these types of communications.

3) Prohibits a person from transmitting, selling, or releasing to a third party, in exchange for remuneration, any prescribing data of a physician, if the physician has placed his or her name on a DO NOT USE list maintained by the Board on its Web-site, and allows the Board to contract with a third party to create or maintain the list.

4) Defines "prescribing data of a physician" as information that sets forth a prescription written by a physician in combination with any item that individually identifies the physician, including a unique identifier assigned for tracing purposes.

5) Allows the Board to impose a reasonable fee upon a physician for the listing of the physician's name on the DO NOT USE list and upon a person for the right to access the information contained on the list.

6) Requires a person transmitting, selling, or releasing any prescribing data as permitted to update its data biannually to ensure that it conforms to the DO NOT USE list.

7) Specifies that a person transmitting, selling, or releasing any prescribing data does not violate the prohibition against providing prescribing data if the physicians name was not on the list when the person initially consulted the list and less than six months have passed since the initial consultation, and if the person performed a biannual update and less than six months have passed since the update was performed.

8) Permits the prescribing data of a physician whose name is on the DO NOT USE list to be transmitted, sold, or released to any third party, in exchange for remuneration, as reasonably necessary, for any of the following purposes:

a) For use in aggregate form if it is not associated with any personal identification of a physician or any unique identifier established for the purpose of tracking an individual physician.

b) To provide the physician with information about a specific drug, which is not included in the package insert approved by the federal Food and Drug Administration (FDA) for the drug, that is essential to the safe use of the product, such as information regarding side effects, contraindications, interactions, and dosing. Promotional material may not, under any circumstances, be provided in combination with this information.

c) To provide the physician with information regarding action by the state or be the FDA limiting or disallowing the sale or use of a specific drug or to voluntarily disclose to the FDA adverse events related to a specific drug or medical device.

d) Use by a licensed health care professional directly related to providing health care to a patient or by a health insurer or health care service plan or its contractor directly related to administering the health care benefit, or for use by programs and procedures related to the treatment of chronic and seriously debilitating or life-threatening conditions, as defined.

e) Research projects or clinical trials for which a physician has expressly authorized the specific release of prescribing data.

FISCAL EFFECT: According to the Assembly Committee on Appropriations Committee analysis, dated May 7, 2003, minor absorbable costs to the Department of Justice. However, recent amendments requiring the Board to maintain a DO NOT USE list, or for the Board to contract with a third party to create or maintain the list, may have costs and staff resources associated with those requirements and the Board would need authorization for those expenditures.

COMMENTS:

1. **Purpose.** This bill contains two major parts, one sponsored by the Office of HIPAA Implementation under the California Health and Human Services Agency relating to CMIA and medical marketing, and the other sponsored by the California Medical Association (CMA) relating to the sale of physician prescribing data.

   a) **CMIA provisions.** The author indicates that California has one of the most complete and comprehensive privacy laws regulating the use of personal health information. Although CMIA limits use of personal health information to the provision of health care services for the patient, it does not specifically define health care services, nor does it address the use of personal health information for marketing-type activities, which leaves the law open for broad interpretation. As argued by the author, current federal regulations and State law thus create a loophole that will allow the use of personal health information for marketing-type activities without control or opt out opportunities for the individual.

   b) **Physician prescribing data provisions.** CMA indicates that currently drug companies pay millions of dollars to purchase from pharmacies the names of doctors and the drugs they have prescribed and then develop a prescribing "profile" of individual physicians, send unsolicited product information and lobby them to change which drugs they prescribe. This practice is an international phenomenon that has prompted Canada and Europe to examine and implement restricted access to this information. According to CMA, with more than 7 million prescriptions filled every month in California, purchasing prescription information is a multi-million dollar industry, and a factor in rising costs of prescription drugs. This measure will combat the sale of physicians' prescribing decisions by establishing a DO NOT USE list similar to the "Do Not Call" list used to restrict telemarketing. Pharmacies would be prevented from selling the prescribing information of any physician who puts their name on the list, unless certain exceptions apply.

2. **Background.**

   a) **Clarification of CMIA with the Federal HIPAA.** The HIPAA was signed into law on August 21, 1996 (PL 104-191). While the primary intent of HIPAA was to improve health insurance accountability for persons changing employers or leaving the workforce entirely, the law also contained administrative simplification provisions that aimed to reduce the administrative burden associated with the transfer of health information between organizations. Under HIPAA, the Secretary of the United State Department of Health and Human Services (HHS) is required to adopt standards for, among other things, privacy of personal health information.

On August 14, 2000, pursuant to this requirement, HHS published its "Standards for Privacy of Individually Identifiable Health Information: Final Rule" (Standards). Under the Standards, in most cases, a health care provider or health plan must first obtain an authorization from the patient for any use of disclosure of protected health information for marketing. However, the definition of marketing was recently amended and threatens to create confusion between HIPAA and CMIA. This bill is intended to address the potential confusion and ensure that California law is clear with respect to the issue of the marketing of medical information.

Under the Standards, marketing information is defined to include situations where a health care provider or health plan discloses protected health information to another entity in exchange for direct or indirect remuneration so that the other entity can make a communication about its own product or services to the patients of the provider or plan. The author points out that in some cases, information is not disclosed to the third party, yet marketing still occurs. For example, the author provided a recent letter sent by Rite Aid to a patient in which the company extolled the virtues of Allegra and encouraged the patient to refill his/her prescription for the drug. The letter notes that the mailing is funded by Aventis Pharmaceuticals and "neither your name or your doctor's name will be given to Aventis Pharmaceuticals." In this case, Rite Aid never disclosed any information to Aventis, yet the pharmacy received remuneration from the pharmaceutical company for the communication.

b) **This measure has been double referred from the Senate Judiciary Committee.** This measure was heard by the Senate Judiciary Committee on July 15, 2003. All issues regarding changes and amendments to the CMIA and marketing of medical information were addressed at that time. However, on July 8, 2003, the bill was amended to include for the first time the provisions sponsored by CMA relating to the sale of physician prescribing data. The language was included in the Business and Professions Code dealing with Pharmacy Law and would have made it unlawful to directly or indirectly sell, or otherwise transfer to any person not directly involved in filling a prescription, any information or data related to a prescription filled by a pharmacy or licensed pharmacist if it contained any identifiable information of the prescribing physician. It required the Board of Pharmacy to take action against the pharmacy or pharmacist who violated this provision.

As indicated by the Judiciary Committee, at issue with this amendment was whether the sale or transfer of physicians' prescribing practices by pharmacists and pharmacies should be regulated. As explained by the Committee, the data, while not individually identifiable to the patient, is aggregated by health research companies and sold to pharmaceutical companies, and used for market studies and targeted marketing efforts. In many cases, pharmaceutical companies will know more than a physician about his prescribing practices, and physicians object that the information violates their professional privacy. In addition, while the practice has no direct impact on consumers and patients, physicians argue that it increases health care costs.

There was strenuous opposition to this amendment by the pharmaceutical companies and companies that aggregate and sell prescription drug data. In discussions with the opponents, the author agreed in concept to a different approach involving an "opt-out" list for physicians. The Committee agreed to allow the bill to move forward but reserved the right to call the bill back to Committee regardless of whether a rule waiver would be needed to prevent the bill from becoming a two-year bill.

This bill was amended once again on July 22, 2003, after being heard by the Judiciary Committee. The language originally placed in the Business and Profession Code pertaining to physician prescribing information was removed, but similar language was placed in the CMIA. This bill was referred to the Senate Business and Professions Committee on July 24, 2003.

On Wednesday, August 13, 2003, the Senate Business and Professions Committee received proposed amendments to this measure regarding the creation of a DO NOT USE list to prevent the sale, transmittal or release of prescribing date of a physician. These amendments are reflected in the August 18, 2003 version of the bill.

c) **The American Medical Association (AMA) has a physician privacy policy.** Physicians who chose not to receive information on the products and/or services offered by pharmaceutical companies may specify this preference as part of the AMA's Do Not Release or Do Not Contact policy. If the physician requests this status, the AMA will prohibit the release of physician identifying information to all entities and their direct affiliates. The Do Not Release policy prohibits the AMA from releasing any information it has on the physician, while the Do Not Contact policy is less stringent and ensures that the physician's name will not be given for marketing purposes. Although the physician will receive health hazard warnings, drug recalls, and AMA related information, their identifying information will not be provided for purposes of distributing drug samples, journals or other promotional materials. However, a pharmaceutical representative may still contact the physician by using information from a source outside of the AMA.

3. **Most Pharmaceutical Companies and Health Research Companies are "Opposed Unless Amended."** IMS Health Incorporated, which is one of the leading providers of information, research, and analysis to the health care industry, is opposed to the creation of a DO NOT USE list and restrictions on use of prescription information proposed by CMA , for the following reasons: (1) these restrictions will have a disparate impact on many different parties in the health care system, with certain organizations benefiting from the

amendment and many organizations adversely impacted by the amendment; (2) it will result in significant financial and economic costs to the health care system at a time when costs are already high; (3) the quality of health care research available to industry, government and academia will be severely, adversely affected; (4) efforts to provide information to physicians that's relevant to their practice will become less efficient, leading to more visits, telephone calls and materials to physicians to ensure important information reaches these physicians; and, (5) there is no evidence that existing guidelines sponsored by the AMA do not work.

Arclight Systems, which is an independent information services company that provides data on, among other things, pharmaceutical product volume and market share, is opposed to the CMA language and makes the following arguments: (1) the restrictions will substantially increase the costs to collect physician prescribing information which has many beneficial uses and adversely impact the quality of information services available to customers; (2) it will force pharmaceutical companies to shift resources into more expensive, less efficient broader-based marketing and advertising programs and will impede generic manufacturers' ability to market generic drugs effectively, which would lead to higher costs for consumers; (3) a new privacy right for physicians in their professional (not personal) capacity is inconsistent with state and Federal court decisions and the HIPAA Privacy Standard; and, (4) disclosure of physician prescription information is protected commercial speech under the First Amendment.

The California Healthcare Institute argues that provisions restricting prescriber data would disrupt established practices utilized by drug manufacturers, physician organizations and medical plans by hindering distribution of free sample medicine to physicians (and ultimately patients), impede placement of clinical trials and prejudice public health studies.

Pharmaceutical companies such as GlaxoSmithKline, Johnson & Johnson, Bristol-Myers Squibb Company, and Cephalon, Inc. argue that CMA complains, with minimal substantiation, that California physicians are confronted by pharmaceutical sales representatives with more precise information regarding physician prescribing practices than is maintained by physicians themselves, and that the information is used in product promotions efforts to which physicians object. As argued by the companies, the obvious solution is for an offended physician simply to advise a sales representative, or their company, to no longer communicate their knowledge of the physician's prescribing practices during a product presentation. The legislation should focus on complaints regarding these practices, not on the status of the prescribing information to accord it "property" status in control of the physician. These amendments will create an unnecessarily elaborate physician "opt-out" process that envisions registration by physicians with the Board to prevent contacts.

4. **Other Policy Issues of Concern.**

a) **Should the Medical Board assume the responsibility for maintaining the DO NOT USE list?** Currently, the Board is required to reduce its budget for Fiscal Year 2003-04 by $1.8 million. The Board has also experienced in the last 13 months, the elimination of 38.5 positions, 13% of its workforce. The Board is currently struggling to maintain its service levels in the face of a growing caseload and has sought additional positions to meet workload and increased responsibilities for new mandates.

Although the Board does not have an official position on the bill, they do have a policy position regarding no new unfunded mandates, especially in light of the major reductions in staffing. It is likely the Board would pursue contracting out both the creation and maintenance of the DO NOT USE list, but it would still cost time and staff resources to process and oversee a contract and in order to pay for the contractor the Board would need authorization to spend the funds. The Board has indicated that language should be added to this measure to read as follows:

"This section shall become operative within 190 days following the appropriation of $120,000 to the Medical Board of California's operating budget for the development or contracting out of the automated systems necessary to effectively maintain and disseminate information contained in the "DO NOT USE" list described in this section."

Also indicated by the Board, that if the language does not give authority to the Board to impose a reasonable fee for use of the listing, then they would have to hold a regulatory hearing to set the fee. The Board suggests that the following language also be included:

"The medical board, by regulation, may impose a reasonable fee."

b) **It is unclear how the prohibition against providing prescribing information of a physician would be enforced.** There are two sections in the Civil Code regarding violations of specific provisions of the CMIA. Section 56.35 provides that a patient whose medical information has been used or disclosed in violation of specified sections of the CMIA and who has sustained economic loss or personal injury may recover compensatory damages, punitive damages not to exceed $3,000, attorneys' fees not to exceed $1,000, and litigation costs. Section 56.36 provides that any violation of the provisions of the CMIA that results in economic loss or personal injury to a patient is punishable as a misdemeanor. In addition, any individual may bring an action against any person or entity who has negligently releases confidential information or records concerning a patient, and any person or entity who negligently discloses "medical information" in violation of the CMIA shall be subject to a fine not to exceed $2,500 per violation, and if intentionally discloses "medical information" a fine not to exceed $25,000 per violation. Any person or entity that intentionally uses the medical information for financial gain shall be liable for a fine not to exceed $250,000 per violation.

Exhibit B Page 13

"Medical information" as defined in the CMIA means any individually identifiable information, in electronic or physician form, in possession of or derived from a provider or health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment.

"Prescribing data of a physician" has been separately defined in the new Section 56.268 of the bill which requires the DO NOT USE list to be maintained. It does not appear as if any of the specified damages or civil remedies and fines of the CMIA would apply to those who may violate Section 56.268, since the definition of "medical information" does not seem to include the physicians prescribing information. Also it should be noted that the restrictions of Section 56.268 would generally apply to pharmacists and pharmacies that currently supply prescribing information. The Board of Pharmacy may take action against a pharmacist for unprofessional conduct if they violate any state law governing pharmacy. It is not clear that violation of the restrictions regarding the sale or release of prescription information of a physician who is on a DO NOT USE list would amount to unprofessional conduct of the pharmacist unless specified as such.

If violations regarding Section 56.268 are to be specified, then the author should consider creating a separate part in the Civil Code rather than under the CMIA, such as "PART 2.65" and renumber the section to "Section 57." It seems clear that the CMIA was intended to apply to patient medical information and not physician prescription information which may or may not be made available to other persons or entities depending on the specified restrictions within Section 56.268.

5. **Similar Legislation This Session.** AB 103 (Reyes) would require a pharmaceutical manufacturing company to annually disclose to the Board of Pharmacy certain information regarding the economic benefits the company provides in connection with its marketing activities, including disclosing the names of the recipients of any benefits and the value, nature, and purpose of the benefits. The bill failed passage on the Assembly Floor and is currently on the Assembly Inactive File.

   AB 1437 (Koretz) would generally require every pharmaceutical manufacturing company to disclose to the State Department of Health Services the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with certain drug marketing activities. The bill has yet to be heard in a policy committee in the Assembly.

6. **Prior Related Legislation.** AB 2191 (Migden, Chapter 853, Statutes of 2002) included pharmaceutical companies in the CMIA disclosure restrictions.

   AB 456 (Speier, Chapter 635, Statutes of 2001), created the California Office of HIPAA Implementation to help identify when state confidentiality and privacy requirements for medical information are more or less stringent than HIPAA.

SUPPORT AND OPPOSITION:

Support: Office of HIPAA Implementation (Sponsor)
California Medical Association (Sponsor)
California Labor Federation
American Civil Liberties Union
California Nurses Association
Consumers Union
Gray Panthers
Orange County Fire Authority
Privacy Rights Clearinghouse
Protection & Advocacy, Inc.
Western Center on Law and Poverty

Oppose Unless Amended:
Amgen
Arclight Systems
AstraZeneca Pharmaceuticals, LP
Bristol-Myers Squibb Company
California Healthcare Institute
California Retailers Association
Cephalon, Inc.
CANJI, Inc.
DNAX Research, Inc.
GlaxoSmithKline
IMS Health Incorporated
Johnson & Johnson
McKesson Corporation
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Quintiles Transnational Corp.
Schering-Plough

Consultant: Bill Gage

EXHIBIT C

SENATE RULES COMMITTEE
Office of Senate Floor Analyses
1020 N Street, Suite 524
(916) 445-6614 Fax: (916) 327-4478

THIRD READING

Bill No: AB 715
Author: Chan (D), et al
Amended: 9/10/03 in Senate
Vote: 21

PRIOR COMMITTEE VOTES NOT RELEVANT

SENATE APPROPRIATIONS COMMITTEE: Senate Rule 28.8

ASSEMBLY FLOOR: Not relevant

SUBJECT: Personal information

SOURCE: Author

DIGEST: Senate floor amendments of 9/8/03 delete contents of the bill and take large portions of AB 262 (Chan), relating to pharmaceutical marketing practices, and place them into this bill. AB 262 passed the Senate Judiciary Committee on a 5-1 vote. (See Analysis section below.)

ANALYSIS: This bill addresses the subject of communications by health care providers and plans to patients, where those communications are paid for by third parties (such as pharmaceutical companies). The provisions generally prohibit remunerated communication, with various exceptions negotiated between the bill's sponsor (the Office of HIPAA Implementation) and representatives of health plans and pharmaceutical companies. First, the bill exempts various communications to health plan enrollees that are needed to inform them of their benefits and plan procedures. Second, the bill exempts various treatment-related communications, so long as those communications are not remunerated. Finally, the bill exempts remunerated "disease management" communications for seriously debilitating or life-

CONTINUED

AB 715 (Chan) **Oppose**
File Item # 133
Assembly Floor: Vote Not Relevant (Gut and Amend)
Senate Education: Vote Not Relevant (Gut and Amend)
Vote requirement: 21
Version Date: 9/10/03

Quick Summary

This bill is a gut and amend on the Senate floor that takes provisions from AB 262 (Chan) and places them into this bill. This bill circumvents the legislative process and can wait until next year to move forward. This bill muddies California's medical privacy law by requiring that a health care provider or health plan contractor obtain a patient's permission before the patient's medical information can be used for marketing purposes. Includes a prohibition on pharmacies providing data to suppliers, which would be used to market directly to physicians.

Fiscal Effect

MINOR COSTS.

State. This bill would have no fiscal impact.

Fiscal Comments
This bill defines communication methods pharmaceutical companies can use when marketing products.

Fiscal Consultant: Sharon Bishop/MM

Digest

Medical Privacy Law Clarification

Prohibits a health care provider and a health care service plan contractor from marketing a patient's medical information for any purpose not necessary to provide health care services unless expressly authorized by the patient.

Requires any such authorization forms be printed in 14-point type.

Defines **"marketing"** as a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

Current federal law, the *Health Insurance Portability and Accountability Act* ("HIPAA"), requires that a health care provider or health plan obtain an authorization from the patient for any use or disclosure of protected health information for marketing, unless the communication is face-to-face communication or is a promotional gift of nominal value.

Existing law requires that specified printed authorizations for the disclosure of medical information be in 8-point type.

Assembly Bill 262 (Chan) of 2003 requires that a health care provider or health plan contractor obtain a patient's permission before the patient's medical information can be used for marketing purposes. Furthermore, the bill creates a DO NOT USE list maintained by the Attorney General whereby pharmaceutical companies may not use information and statistics about individual physicians' prescribing proscribing for marketing purposes, and authorizes the Attorney General to **charge physicians a fee** for inclusion on the list. (Pending in Senate Rules)

Senate Bill 598 (Machado) of 2003 revises and further limits the circumstances under which a provider of health care, health care service plan, or contractor may release medical information that relates to the patient's participation in outpatient treatment with a psychotherapist unless specifically authorized by the patient or the patient's representative for each release. Currently pending in Assembly Judiciary. Senate Floor Vote: 25-12 (AYE: Aanestad and McPherson; NO: All other Republicans except ABS: Morrow)

Assembly Bill 2191 (Migden) of 2002 prohibits pharmaceutical companies or their representatives from disclosing medical information without first obtaining an authorization. Also it requires pharmaceutical companies or their representatives to adhere to specified procedures regarding the maintenance, disposal, and release of medical information and records. Senate Floor Vote: 27-12 (AYE: McPherson; NO: All other Republicans).

Senate Bill 456 (Speier) of 2001, the *Health Insurance Portability and Accountability Implementation Act of 2001*, created the California Office of HIPAA Implementation (CalOHI) within the Health and Human Services Agency. CalOHI was created to assume leadership for the State's HIPAA activities, including identifying when state confidentiality and privacy requirements for medical information are more or less stringent than HIPAA. Senate Republican Members' vote: 4-7 (AYE: Aanestad, Ashburn, McPherson, Margett; NO: Ackerman, Battin, Brulte, Knight, McClintock, Morrow, Oller; ABS: Hollingsworth, Johnson , Poochigian).

Senate Rule 38.5 provides that every amendment proposed must be germane. In order to be germane, an amendment must relate to the same subject as the original bill, resolution, or other question under consideration.

It is beyond dispute that medical information should be protected. This bill would provide more protection for health information; however, it may constrain appropriate activities, including reminders about prescriptions. Furthermore, this bill keeps changing and modifying how it will address the problem it is attempting to remedy. There is no urgency for the government to intervene in this matter.

Support & Opposition Received

Support:
American Civil Liberties Union (ACLU)
California Medical Association
California Office of HIPAA Implementation
Consumers Union
Privacy Rights Clearinghouse
Protection & Advocacy, Inc.
Western Center on Law and Poverty

Opposition:
Astra-Zeneca Pharmaceuticals
Glaxo-Smith-Kline
Canji, Inc.
Johnson and Johnson
Note: All oppose unless amended as of version 9/8/03.

Senate Republican Office of Policy/ *Martin Ruano*

EXHIBIT D

management organization, as defined in Section 1399.900 of the Health and Safety Code, that complies fully with the physician authorization requirements of Section 1399.902 of the Health and Safety Code, provided that the health care service plan or its contractor provides or has provided a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians. Nothing in this paragraph shall be construed to require physician authorization for the care or treatment of the adherents of any well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

(18) The information may be disclosed, as permitted by state and federal law or regulation, to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions, as authorized or required by state or federal law or regulation.

(d) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient.

(e) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no contractor or corporation and its subsidiaries and affiliates shall further disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan or insurer or self-insured employer received under this section to any person or entity that is not engaged in providing direct health care services to the patient or his or her provider of health care or health care service plan or insurer or self-insured employer.

(Added by Stats.2000, c. 1068 (A.B.1836), § 1.16, operative Jan. 1, 2003. Amended by Stats.2002, c. 123 (A.B.1958), § 1, operative Jan. 1, 2003; Stats.2003, c. 562 (A.B.715), § 2; Stats.2006, c. 874 (S.B.1430), § 2.)

Historical and Statutory Notes

Addition of a section of this number by §§ 1.9, 1.10, 1.11, 1.12, 1.13, 1.14 and 1.15 of Stats.2000, c. 1068, failed to become operative under the provisions of § 5 of that Act.

Stats.2002, c. 123 (A.B.1958), in subd. (b), inserted a new par. (8) and renumbered as par. (9) former par. (8); and, in subd. (c), added "when requested for all purposes not included in paragraph (8) of subdivision (b)", at the end of par. (6), and made nonsubstantive changes in par. (15).

The 2002 amendment of this section by c. 123 explicitly amended the 2000 addition of this section by c. 1068, § 1.16.

Stats.2003, c. 562 (A.B.715), in subd. (d), inserted "use for marketing," and made a nonsubstantive change; and deleted subd. (f), which had read: "(f) This section shall become operative January 1, 2003."

For letter of intent regarding Stats.2003, c. 562 (A.B.715), see Historical and Statutory Notes under Civil Code § 56.05.

Stats.2006, c. 874 (S.B.1430), in subd. (c), added par. (18) relating to disclosure to government officials and made a nonsubstantive change to correct grammar.

Section 1 of Stats.2006, c. 874 (S.B.1430), provides: